

Presented to the Court by the foreman of the Grand Jury in open Court, in the presence of the Grand Jury and FILED in the U.S. DISTRICT COURT at Seattle, Washington.

July 24 1920
WILLIAM M. McCOOL, Clerk
By  Deputy

UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA,

Plaintiff,

V.

RAJNINDER JUTLA.

Defendant.

NCR19-141 RSM

INDICTMENT

The Grand Jury charges that:

I. BACKGROUND

At all times material and relevant to this Indictment:

1. RAJNINDER JUTLA was a physician licensed to practice medicine in the states of Washington and Oregon. RAJNINDER JUTLA was a medical board certified anesthesiologist and pain management specialist.

2. RAJNINDER JUTLA was the owner and manager of Mind Your Body Clinic PLLC (“Mind Your Body Clinic”), which had locations in Washington, including its primary location in Seattle, as well as a location in Lake Oswego, Oregon.

A. Insys and Subsys

3. Insys Therapeutics, Inc. ("Insys") was a company incorporated in Delaware and headquartered in Chandler, Arizona.

4. John Kapoor was the founder and owner of Insys.

1 5. Michael Babich held executive management positions at Insys, including
 2 President and Chief Executive Officer.

3 6. Alec Burlakoff held various executive management positions in Insys,
 4 including Vice President of Sales.

5 7. Richard Simon held various executive management positions in Insys,
 6 including Regional Sales Manager for the Central Region and National Director of Sales.

7 8. K.W. was employed by Insys as a Specialty Sales Professional (“SSP”) and
 8 was eventually promoted to the position of District Sales Manager (DSM). K.W.’s roles
 9 and responsibilities as an SSP included marketing Insys and the drug Subsys to
 10 healthcare providers in Washington and Oregon.

11 9. On or about January 4, 2012, the Food and Drug administration (“FDA”)
 12 approved Insys’s application to market a drug called Subsys to patients suffering from
 13 breakthrough cancer pain. Breakthrough cancer pain is a sudden, short-term increase in
 14 pain that may occur in patients who have chronic pain from cancer.

15 10. Subsys was a potent opioid containing fentanyl that was designed to rapidly
 16 enter a patient’s bloodstream upon being sprayed under the tongue. Fentanyl is a
 17 synthetic opioid that is classified as a Schedule II controlled substance under the
 18 Controlled Substances Act. It is primarily used as a pain relief medication. Fentanyl
 19 produces effects similar to the opioids morphine and heroin, but fentanyl has a greater
 20 potency and a shorter duration of action. Fentanyl is rapidly distributed to the brain,
 21 heart, lungs, kidneys and spleen.

22 11. Drugs like Subsys which contain fentanyl are highly addictive and can lead
 23 to physical and/or psychological dependence, abuse and addiction.

24 12. Due to the potency of Subsys and the potential for addiction, the FDA
 25 approved the use of the drug solely for “the management of breakthrough pain in cancer
 26 patients 18 years of age and older who are already receiving and who are already tolerant
 27 to opioid therapy for their underlying persistent cancer pain.”

1 13. As a fentanyl product, Subsys had a high risk of misuse, abuse, addiction
 2 and overdose. To reduce these risks, on December 28, 2011, the FDA approved a single,
 3 shared system Risk Evaluation and Mitigation Strategy (REMS) for the entire class of
 4 transmucosal immediate-release fentanyl (TIRF) prescription medicines. This “TIRF
 5 REMS” Access Program, consisted of a restricted distribution program. Accordingly, in
 6 each instance in which a patient was prescribed Subsys, both the prescriber and the
 7 patient were required to complete and submit a Patient-Prescriber Agreement Form
 8 detailing the risks and obligations imposed on both parties when a fentanyl product was
 9 prescribed.

10 14. Before prescribing a TIRF drug like Subsys to a patient, the prescriber was
 11 required to complete and sign a REMS form which explicitly stated, “I understand that
 12 TIRF medications are indicated only for the management of breakthrough pain in patients
 13 with cancer who are already receiving, and who are tolerant to, around-the-clock opioid
 14 therapy for their underlying persistent pain.”

15 15. Virtually all of Insys’s profits came from the prescribing of Subsys by
 16 health care providers in the United States. Subsys was profitable for the company. In
 17 2015, for example, Insys reported approximately \$330 million in revenue from Subsys.

18 16. Subsys was approved for use in dosages of 100, 200, 400, 600, 800, 1200
 19 or 1600 micrograms. Patients were supposed to take one dose of Subsys per episode of
 20 breakthrough cancer pain and were required to wait four hours to take another dose of the
 21 drug if experiencing breakthrough pain. Further, patients were instructed to limit the
 22 amount of Subsys they took to four or fewer doses per day.

23 17. Subsys was expensive. Depending upon the dosage and number of units
 24 prescribed, a prescription for Subsys usually cost thousands of dollars per month. Most
 25 patients relied upon commercial insurance and/or publicly-funded insurance, including
 26 Medicare and Medicaid, to subsidize the cost of Subsys.

1 **B. The Medicare Program and Subsys**

2 18. The Medicare Program was established in 1965 pursuant to amendments to
 3 the Social Security Act. The Medicare Program was a health care benefit program that
 4 provided basic health insurance coverage to certain disabled persons as well as to
 5 individuals 65 years or older. Eligible persons could elect to participate in the program
 6 by completing an application and either agreeing to pay a premium for Medicare benefits,
 7 or arranging for a third party to pay such premiums. Persons enrolled in the Medicare
 8 programs are hereinafter referred to as “beneficiaries.” Medicare was a “federal health
 9 care program” under 42 U.S.C. § 1320a-7b(f).

10 19. The Medicare Program also included a prescription drug program known as
 11 “Part D,” which was funded by insurance premiums paid by enrolled Medicare
 12 beneficiaries and contributions from the federal treasury. The Part D program was
 13 administered by various “Plan Sponsors,” each of which dictated the specific drugs it
 14 would cover and how much it would pay for those medications. The Centers for
 15 Medicare and Medicaid Services (“CMS”), through the federal treasury, reimbursed the
 16 Part D Plan Sponsors for the covered drugs.

17 20. In Washington, there were numerous Plan Sponsors that covered state
 18 residents, including but not limited to Aetna, Cigna, Humana, United Health Care, and
 19 Regence Blue Shield.

20 21. Many Plan Sponsors as well as private insurance companies contracted
 21 with Pharmacy Benefit Managers (PBMs), which handled the administration of the
 22 prescription drug benefit on behalf of the Medicare Part D Plan Sponsors and private
 23 insurance companies.

24 22. Most of the above-listed Medicare Plan Sponsors and PBMs administering
 25 Part D plans for them would only approve payment for Subsys that was prescribed to a
 26 Medicare patient if certain criteria were met, including (i) that the patient had a diagnosis
 27 of cancer, (ii) that the use of Subsys was for breakthrough cancer pain, and, in most
 28

1 cases, (iii) that other strong-acting narcotic pain relievers had been tried and been
2 ineffective, not tolerated or contraindicated.

3 23. Medicare would not pay for medications if the prescriptions were written in
4 exchange for a bribe or kickback.

5 **C. Private Insurance Companies and Subsys**

6 24. BlueCross/BlueShield of Illinois, Cigna Health Care, United Health Care,
7 Moda Health Insurance and Regence Blue Shield, among others, were each private
8 insurers and “health care benefit programs” under 18 U.S.C. § 24(b) that provided health
9 insurance benefits to their members in exchange for the payment of premiums.

10 25. Many private insurers contracted with PBMs to administer prescription
11 drug benefits for their members. Express Scripts and OptumRx were PBMs that
12 contracted with Plan Sponsors to administer the prescription drug benefit for Medicare
13 Plan Sponsors and private insurers. Each was a health care benefit program under 18
14 U.S.C. § 24(b).

15 26. The above-listed private insurance companies and PBMs only approved
16 payment for Subsys that was prescribed to a plan member if certain criteria were met,
17 including (i) that the patient had a diagnosis of cancer, (ii) that the use of Subsys was for
18 breakthrough cancer pain, and, in most cases, (iii) that other strong-acting narcotic pain
19 relievers had been tried and been ineffective, not tolerated or contraindicated.

20 **D. Prior Authorization Procedure**

21 27. Because of the high cost of Subsys, almost all of the Medicare Plan
22 Sponsors, private insurance companies, and PBMs required providers to obtain
23 authorization prior to the filling of a Subsys prescription. Providers were typically
24 required to prepare and complete written prior authorization requests in which
25 information concerning the patient and his or her relevant diagnosis for which Subsys

1 was prescribed, including the ICD-9 code,¹ was provided. On the prior authorization
 2 request form, the provider also confirmed whether the patient was opioid tolerant and
 3 whether other short-acting narcotics had been tried and proven ineffective. Upon receipt
 4 of a completed prior authorization form, the Plan Sponsor, PBM, or private insurance
 5 company made a determination as to whether it would approve payment for the Subsys
 6 prescription.

7 **E. Insys Reimbursement Center**

8 28. In or about January 2013, due to the difficulty doctors were having in
 9 obtaining approval for Subsys from insurance companies, Insys established a group
 10 known as the Insys Reimbursement Center (“IRC”). The IRC comprised a group of Insys
 11 employees based in Arizona who specialized in obtaining approval from insurance
 12 companies for payment for Subsys.

13 29. Practitioners using the IRC were required to provide Insys with detailed
 14 information for all patients prescribed Subsys. This information was provided on an
 15 “Insys Reimbursement Center Patient Authorization & Referral Form” (“Opt-in Form”),
 16 which included confidential patient information such as the name, date of birth, insurer
 17 information, the medical diagnosis or diagnoses for which Subsys was being prescribed,
 18 and the corresponding ICD-9 code associated with the diagnosis, as well as additional
 19 information in support of the prior authorization in a section titled “Rationale for Prior
 20 Authorization.”

21 30. At Mind Your Body Clinic, Insys employees typically completed the
 22 Opt-in Forms based on the patient’s medical chart notes and/or information
 23 communicated to them by RAJNINDER JUTLA. RAJNINDER JUTLA then typically
 24 signed the Opt-in Forms. The completed Opt-in Forms were then faxed or emailed to the
 25
 26

27 28 ¹ ICD-9 stands for the International Statistical Classification of Disease and Related Health Problems 9th Revision
 (“ICD-9”). There was a recognized ICD-9 code for each medical diagnosis. Medical facilities, practitioners,
 insurers, PBMs, government entities and pharmacies employed ICD-9 codes to classify diseases and injuries.

1 IRC, which would then use the information provided and initiate the prior authorization
 2 process with the Plan Sponsor, insurance company, or PBM.

3 31. RAJNINDER JUTLA elected to use the services of the IRC beginning no
 4 later than January 2014 for the vast majority of prior authorizations for her Subsys
 5 prescriptions.

6 32. Most of RAJNINDER JUTLA's Opt-in Forms contained the following
 7 certification signed by RAJNINDER JUTLA: "I certify that the above therapy is
 8 medically necessary and to the best of my knowledge all information represented herein
 9 is accurate and complete."

10 **F. Insys Speaker Program**

11 33. In 2012, Insys established a program, called the Insys Speaker Program
 12 ("ISP" or "Speaker Program"), in which doctors and other qualified health care providers
 13 would be compensated for purportedly providing educational programs concerning
 14 Subsys to other health care providers. The purported purpose of the Speaker Program
 15 was to gather licensed health care professionals who had capacity to prescribe Subsys and
 16 educate them about the drug.

17 34. Many of the ISP "presentations" took place at high-end restaurants, at
 18 which the presenter would purportedly speak about the benefits of Subsys. Insys paid for
 19 the cost of the meal for all attendees, up to \$125 per person. In addition, Insys paid the
 20 speaker a flat fee, ranging from \$800 to \$3700 per program.

21 35. At various dates between 2012-2016, Insys hired third party companies
 22 Scimedica, Inc. ("Scimedica") and Plan 365, Inc. ("Plan 365"), to manage the ISP. In
 23 exchange for a fee, these companies made arrangements with the various restaurants
 24 where the purported presentations were held and made payments to the restaurants and
 25 the speakers. The sales representative assigned to the region was required to attend each
 26 speaking program and was required to submit a receipt, sign-in sheet and evaluation form
 27 for each program. Scimedica, Plan 365 or Insys would then issue payment to the
 28 purported speaker at the program.

COUNT 1
(Conspiracy to Pay and Receive Kickbacks)

36. The Grand Jury realleges and incorporates by reference preceding paragraphs 1-35 as if fully set forth herein.

A. The Conspiracy

37. From in or about February 2012 through in or about October 2016, at Seattle, in the Western District of Washington, and elsewhere, defendant RAJNINDER JUTLA did knowingly and willfully conspire and agree with employees, representatives and agents of Insys, who are known and unknown to the Grand Jury and who acted on behalf of Insys, to commit an offense against the United States, namely to knowingly and willfully offer, pay, solicit, and receive any remuneration, directly and indirectly, overtly and covertly, in cash and in kind, in return for purchasing and ordering, and arranging for and recommending the purchasing and ordering of goods, services, and items, that is, Subsys prescriptions, for which payment was made in whole and in part by a Federal Health Care Program, namely, Medicare, contrary to 42 U.S.C. § 1320a-7b(b)(1)(B), (2)(B).

B. Object of the Conspiracy

38. The object of the conspiracy was the unlawful payment kickbacks to RAJNINDER JUTLA and receipt of kickbacks by RAJNINDER JUTLA to induce, and in return for, her prescribing Subsys to her patients, including those who were Medicare beneficiaries.

C. Manner and Means of the Conspiracy

39. Due to the limited number of patients in the United States suffering from breakthrough cancer pain, Insys, by and through its officers, managers and employees, designed and implemented a strategy aimed at inducing health care providers to prescribe Subsys for pain that was caused by conditions other than cancer. A primary target group for Insys officials was pain specialists who, like RAJNINDER JUTLA, were treating a

1 large volume of patients who were experiencing pain from a variety of medical
 2 conditions.

3 40. In order to induce pain specialists and other providers to prescribe Subsys
 4 to patients who were not suffering from breakthrough cancer pain, Insys created the ISP
 5 in 2012. Insys officials publically claimed that the purpose of the ISP was to educate
 6 other providers concerning the benefits of Subsys. In reality, the primary purposes of the
 7 Speaker Program were to provide a financial reward to providers who were prescribing
 8 Subsys and to incentivize those providers to continue to prescribe Subsys in the future.

9 41. Senior officials and managers of Insys regularly informed company sales
 10 representatives that they should expect a “return on the investment” given to doctors who
 11 were part of the Speaker Program and that they should inform these doctors that they
 12 would not obtain any future Speaker Programs if they did not continue to prescribe
 13 Subsys.

14 42. On February 16, 2012, RAJNINDER JUTLA entered a consulting
 15 agreement with Insys, which required RAJNINDER JUTLA to attend a Consultant
 16 Meeting on or about March 23-24, 2012, in Scottsdale, Arizona. RAJNINDER JUTLA
 17 was reimbursed \$1,500 for attending the Consultant Meeting, in addition to travel and
 18 lodging costs.

19 43. In or around July 2012, RAJNINDER JUTLA was approved by Insys to
 20 become an ISP speaker.

21 44. In or around July 2012, October 2013, and March 2014, RAJNINDER
 22 JUTLA entered into written agreements with Insys wherein she agreed to be paid to
 23 provide Speaker Programs. In the contracts, RAJNINDER JUTLA falsely represented
 24 that the Speaker Programs would be “of a professional quality conforming to generally
 25 accepted industry standards and practices.” RAJNINDER JUTLA further falsely
 26 represented that the Speaker Program honoraria she received from Insys would be
 27 consistent with “fair market value” and would not affect her decisions about prescribing
 28 Subsys.

1 45. RAJNINDER JUTLA began prescribing Subsys to her patients in or around
 2 March 2012, and began receiving payments from Insys for Speaker Programs in
 3 November 2012.

4 46. Insys representatives, including Alec Burlakoff, Richard Simon, and K.W.,
 5 assigned speaker programs based on a speaker's volume of Subsys scripts written.

6 47. At a date on or after November 2012, Richard Simon told RAJNINDER
 7 JUTLA that the number of ISP events allocated to her would be based on the number of
 8 Subsys prescriptions RAJNINDER JUTLA wrote. RAJNINDER JUTLA understood that
 9 the number of Speaker Programs allocated to her would be based on the number of
 10 Subsys prescriptions she wrote.

11 48. In order to increase her remuneration from Insys, RAJNINDER JUTLA
 12 actively sought out more and more Speaker Programs from Insys.

13 49. From November 2012 through June 2016, RAJNINDER JUTLA gave
 14 approximately 54 purported ISP presentations at various restaurants and other locations.
 15 For each of these purported presentations, RAJNINDER JUTLA was paid a fee of
 16 between \$800 and \$3,700. In total, RAJNINDER JUTLA received more than \$109,000
 17 from Insys in compensation for purportedly speaking about Subsys.

18 50. In exchange for speaker fees and free meals, RAJNINDER JUTLA wrote
 19 more prescriptions for Subsys, including prescriptions that were paid for by Medicare.
 20 Between 2012 and 2015, RAJNINDER JUTLA was one of the top prescribers of Subsys
 21 in the State of Washington. During the years RAJNINDER JUTLA participated in the
 22 Speaker Program, the number of prescriptions she wrote fluctuated, in accordance with
 23 her payments from Insys. For example:

24 a. In 2012, Insys paid RAJNINDER JUTLA approximately \$7,200. In
 25 that same year, RAJNINDER wrote approximately 24 prescriptions for Subsys.

26 b. In 2013, Insys paid RAJNINDER JUTLA approximately \$26,500.
 27 In that same year, RAJNINDER JUTLA wrote approximately 129 prescriptions for
 28 Subsys.

c. In 2014, Insys paid RAJNINDER JUTLA \$35,400. In that same year, RAJNINDER JUTLA wrote approximately 210 prescriptions for Subsys.

d. In 2015, Insys paid RAJNINDER JUTLA \$32,400. In that same year, RAJNINDER JUTLA wrote approximately 158 prescriptions for Subsys.

e. In 2016, Insys paid RAJNINDER JUTAL \$8,300. In that same year, RAJNINDER JUTLA wrote approximately 22 prescriptions for Subsys.

Sham Speaker Programs

51. Many of RAJNINDER JUTLA's Speaker Programs were sham programs, examples of which are described below:

a. Individuals who were friends and/or colleagues of RAJNINDER JUTLA, attended multiple Speaker Programs, at some of which RAJNINDER JUTLA made no presentation about Subsys. Because all legitimate Speaker Programs required the use of an identical, or nearly identical, pre-approved slide presentation, there was no educational purpose for health care professionals to attend Speaker Programs on a repeated basis.

b. One individual, M.Z., a personal friend of RAJNINDER JUTLA's, attended ten Speaker Programs between December 2012 and February of 2015, including four at which M.Z. was the sole provider present other than RAJNINDER JUTLA. RAJNINDER JUTLA was paid \$7,600 for these four purported Speaker Programs.

c. On or about August 30, 2013, RAJNINDER JUTLA, K.W., and L.M. and S.S., personal friends of RAJNINDER JUTLA's, had dinner at a high-end restaurant in Portland, Oregon to celebrate L.M.'s birthday. L.M. was the only provider attendee at the dinner other than RAJNINDER JUTLA. Later, RAJNINDER JUTLA forged the signature of L.M. on a Speaker Program sign-in sheet for the date and location of the dinner, after L.M. declined to sign the sign-in sheet because it had been a birthday dinner, not a Speaker Program. RAJNINDER JUTLA was paid \$800 for this purported Speaker Program.

1 d. On or about September 5, 2013, RAJNINDER JUTLA conducted a
 2 purported Speaker Program at which there were no attendees, other than RAJNINDER
 3 JUTLA, who were authorized under Washington State law to prescribe controlled
 4 substances. RAJNINDER JUTLA was paid \$1600 for this purported Speaker Program.

5 ***False and Fraudulent Medical Records and Opt-In Forms***

6 52. RAJNINDER JUTLA and K.W. met frequently in order to discuss new
 7 patients for whom RAJNINDER JUTLA could prescribe Subsys or patients already
 8 receiving Subsys for whom she could increase the dosage.

9 53. RAJNINDER JUTLA often prescribed Subsys for “off-label” uses,
 10 meaning patients who were suffering from a wide variety of ailments and not necessarily
 11 from breakthrough pain due to cancer.

12 54. RAJNINDER JUTLA knew that the number of Speaker Programs, and
 13 consequently, speaking fees, she received was dependent on the number of Subsys
 14 prescriptions she wrote that were ultimately authorized and paid for by insurance
 15 companies.

16 55. In order to obtain Speaker Programs and the associated remuneration from
 17 Insys, RAJNINDER JUTLA regularly provided and caused to be provided false and
 18 fraudulent information to Plan Sponsors, PBM's and insurance companies to obtain
 19 insurance coverage for Subsys prescriptions, including but not limited to false and
 20 misleading information regarding (a) historical cancer diagnoses; (b) the ICD-9 diagnosis
 21 code associated with the Subsys prescription; and, (c) the effectiveness of other
 22 medications that had been tried and failed. By providing and causing to be provided false
 23 information to insurance companies, Plan Sponsors and PBM's, RAJNINDER JUTLA
 24 caused and intended to cause those entities to issue prior authorizations and pay for her
 25 patients' Subsys prescriptions, which, in turn, generated increased profits to Insys, and
 26 increased remuneration, in the form of honoraria for Speaker Programs and free meals, to
 27 RAJNINDER JUTLA.

1 56. RAJNINDER JUTLA told patients that a prior cancer diagnoses would
 2 justify insurance coverage of Subsys, notwithstanding the fact that the patients were not
 3 suffering any pain due to the historical cancer, and it was not the purpose for which the
 4 patients saw RAJNINDER JUTLA, nor the purpose for which RAJNINDER JUTLA
 5 prescribed Subsys.

6 57. The following sub-paragraphs are representative examples of false
 7 statements and misrepresentations made by RAJNINDER JUTLA in patient medical
 8 chart notes and Opt-in Forms for the purpose of obtaining prior authorization and
 9 insurance coverage for Subsys prescriptions she wrote:

10 a. Patient B.A. saw RAJNINDER JUTLA for treatment of her chronic
 11 pain and fibromyalgia. B.A. was not treated by RAJNINDER JUTLA for cancer or any
 12 cancer-related condition. On or about June 20, 2014, RAJNINDER JUTLA prescribed
 13 Subsys to B.A. On that same date, RAJNINDER JUTLA listed the ICD-9 code 338.3
 14 (neoplasm related pain²) and cervical dysplasia in B.A.'s medical chart for the first time.
 15 On July 17, 2014, RAJNINDER JUTLA completed an Opt-in Form listing the ICD-9
 16 code 338.3 as one of the diagnosis codes in support of the prior authorization for Subsys.

17 b. Patient D.L. saw RAJNINDER JUTLA for chronic pain in her neck,
 18 as the result of an injury. D.L. has never had cancer and was not treated by RAJNINDER
 19 JUTLA for cancer or any cancer-related condition. On or about May 5, 2014,
 20 RAJNINDER JUTLA prescribed Subsys to D.L. On that same date, RAJNINDER
 21 JUTLA listed ICD-9 code 338.3 and fibromas in D.L.'s medical chart for the first time.
 22 On or about May 5, 2014, RAJNINDER JUTLA signed an Opt-in Form listing ICD-9
 23 code 338.3 and "breast mass" in support of the prior authorization for Subsys.

24 c. Patient J.W. saw RAJNINDER JUTLA for chronic pain related to

27 2 According to the National Cancer Institute, a neoplasm is an abnormal mass of tissue that results when cells divide
 28 more than they should or do not die when they should. Neoplasms may be benign (not cancer), or malignant
 (cancer). A neoplasm can also be called a tumor.

1 work accidents and fibromyalgia. J.W. has never had cancer and was not treated by
 2 RAJNINDER JUTLA for cancer or any cancer-related condition. On or about April 25,
 3 2014, RAJNINDER JUTLA prescribed Subsys to J.W. On that same date, RAJNINDER
 4 JUTLA listed ICD-9 code 338.3 and uterine fibroids in J.W.'s medical chart note for the
 5 first time.

6 58. During the aforementioned timeframe for the conspiracy from
 7 approximately March 2012 through October 2016, RAJNINDER JUTLA wrote more
 8 than 540 prescriptions for Subsys, including more than 80 prescriptions for patients
 9 covered by Medicare. Medicare paid more than \$620,000 for these prescriptions.

10 **D. Acts in Furtherance of the Conspiracy (Overt Acts)**

11 59. In furtherance of the conspiracy and to accomplish its objectives and
 12 purposes, the following acts, among others, were committed by one or more of the
 13 co-conspirators in the Western District of Washington and elsewhere:

14 60. On or about October 9, 2014, RAJNINDER JUTLA met with some
 15 individuals at the Capital Grille in Seattle, Washington, where she purportedly spoke
 16 about Subsys. The only attendee at the dinner, other than Insys employees, was
 17 RAJNINDER JUTLA's friend M.Z. The dinner was M.Z.'s ninth ISP presentation
 18 attended.

19 61. On or about October 14, 2014, RAJNINDER JUTLA received check
 20 number 27111 issued by Plan 365 Inc., in the amount of \$2,200, as payment for the
 21 October 9, 2014, ISP event.

22 62. On or about February 10, 2015, RAJNINDER JUTLA met with some
 23 individuals at Capital Grille in Seattle, Washington, where she purportedly spoke about
 24 Subsys. The only attendee at the dinner, other than Insys employees, was RAJNINDER
 25 JUTLA's friend M.Z. The dinner was M.Z.'s tenth ISP presentation attended.

63. On or about February 18, 2015, RAJNINDER JUTLA received check number 29358 issued by Plan 365, Inc., in the amount of \$2,200, as payment for the February 10, 2015, ISP event.

64. On or about May 8, 2015, RAJNINDER JUTLA signed and caused to be submitted to the IRC an Opt-in Form for patient K.W. that falsely listed ICD-9 code 338.3 (neoplasm related pain) as one of the diagnosis codes in support of the prior authorization, and falsely listed a history of cervical cancer as a rationale for the prior authorization.

65. On or about June 26, 2015, JUTLA signed and caused to be submitted to the IRC an Opt-in Form for patient S.G. that falsely listed ICD-9 codes V10.51 (history of bladder cancer), and 338.3 (neoplasm related pain) as two of the diagnosis codes in support of the prior authorization, and falsely listed “pelvic pain residual from cancer” as a rationale for the prior authorization.

All in violation of 18 U.S.C. § 371.

COUNTS 2-4 (Receipt of Kickbacks)

66. The Grand Jury realleges and incorporates by reference paragraphs 1- 65 above as if fully set forth herein.

67. In exchange for prescribing Subsys to her patients and increasing the dosage of Subsys prescribed to her patients, including but not limited to those prescriptions reimbursed by Medicare, RAJNINDER JUTLA was paid compensation by Insys.

68. Insys funneled money to RAJNINDER JUTLA by paying her for purported Speaker Programs RAJNINDER JUTLA provided, ostensibly to other health care professionals, concerning Subsys. This money was paid to RAJNINDER JUTLA to reward her for prescribing Subsys to her patients, to incentivize her to continue to prescribe Subsys to new patients, and to increase the dosages of Subsys she prescribed to existing patients.

69. On or about the dates listed below, at Seattle, in the Western District of Washington, and elsewhere, RAJNINDER JUTLA did knowingly and willfully solicit and receive the remuneration listed below, directly and indirectly, overtly and covertly, in cash and in kind, in return for purchasing and ordering, and arranging for and recommending the purchasing and ordering of goods, services, and items, that is Subsys prescriptions, for which payment was made in whole or in part by a Federal health care program, specifically, Medicare:

Count	Date Payment Received by RAJNINDER JUTLA	Payment Amount	Date and Place of Purported Speaking Program
2	On or about August 20, 2014	\$2,200	August 13, 2014 at the Capital Grille, Seattle, Washington.
3	On or about October 14, 2014	\$2,200	October 9, 2014 at the Capital Grille, Seattle, Washington.
4	On or about February 18, 2015	\$2,200	February 10, 2015 at the Capital Grille, Seattle Washington.

All in violation of 42 U.S.C. § 1320a-7b(b)(1)(B).

COUNTS 5-12
(Health Care Fraud)

70. The Grand Jury realleges and incorporates by reference paragraphs 1-69 above as if fully set forth herein.

A. The Scheme

71. Beginning in or about February 2012, and continuing until about October 2016, at Seattle, in the Western District of Washington, and elsewhere, the defendant, RAJNINDER JUTLA, knowingly and willfully executed and attempted to execute a scheme and artifice to defraud any health care benefit program, and to obtain money from any health care benefit program, by means of materially false and fraudulent pretenses,

1 representations, and promises, in connection with the delivery of and payment for health
 2 care benefits, items and services.

3 **B. Manner and Means**

4 72. RAJNINDER JUTLA knew that the number of Speaker Programs, and
 5 consequently, speaking fees, she received was dependent on the number of Subsys
 6 prescriptions she wrote that were ultimately authorized and paid for by insurance
 7 companies.

8 73. It was part of the scheme that RAJNINDER JULTA prescribed Subsys to
 9 numerous patients who did not currently have cancer or breakthrough cancer pain.

10 74. It was a further part of the scheme that RAJNINDER JUTLA included
 11 historical cancer diagnoses and ICD-9 codes corresponding to cancer-related diagnoses
 12 and neoplasm-related pain in medical records for patients who did not currently have
 13 cancer, cancer-related pain, or neoplasm-related pain, and who were not seeing
 14 RAJNINDER JUTLA for treatment of cancer, cancer-related pain, or neoplasm-related
 15 pain. RAJNINDER JUTLA included these items in the medical records of those patients
 16 to whom she prescribed Subsys for the sole and express purpose of causing insurance
 17 coverage and insurance payments for Subsys.

18 75. Upon review of patients' medical records and based on instructions from
 19 RAJNINDER JUTLA, RAJNINDER JUTLA's office staff, as well as Insys sales
 20 representatives, including J.H. and K.W., included these historical cancer diagnoses and
 21 ICD-9 codes, on Opt-in Forms, with the intent that the forms would be used by the IRC
 22 as part of the prior authorization process for Subsys.

23 76. It was a further part of the scheme that RAJNINDER JUTLA signed and
 24 submitted or caused to be submitted Opt-in Forms for Subsys to the IRC with the
 25 understanding that that information would be provided to Plan Sponsors, PBMs, and
 26 insurance companies. These Opt-in Forms falsely represented the diagnosis code
 27 associated with the Subsys prescription was 338.3 (neoplasm related pain), or listed a
 28 historical or non-existent cancer diagnosis as a rationale for the prior authorization. In

1 truth and in fact, RAJNINDER JUTLA knew full well that these patients did not
2 currently have cancer and were not suffering from breakthrough cancer pain when she
3 submitted and caused to be submitted the Opt-in Forms to the IRC. Some of these
4 patients never had any form of cancer. Others had previously been diagnosed with
5 cancer but had recovered, were in complete remission, and were suffering from pain
6 unrelated to their prior cancer diagnosis.

7 77. It was a further part of the scheme that RAJNINDER JUTLA submitted or
8 caused to be submitted fraudulent prior authorization requests for Subsys and Opt-in
9 Forms to the IRC falsely stating that other short-acting narcotics had been tried and
10 proven ineffective.

11 78. It was a further part of the scheme that, based in part on RAJNINDER
12 JUTLA's false and fraudulent representations, the Plan Sponsors, PBMs and insurance
13 companies approved the payment for Subsys for numerous of RAJNINDER JUTLA's
14 patients who were not suffering from breakthrough cancer pain, causing hundreds of
15 thousands dollars in losses to Medicare, Plan Sponsors, PBM's and the insurance
16 companies.

17 **C. Executions of the Scheme**

18 79. On or about the dates set forth below, at Seattle, in the Western District of
19 Washington, and elsewhere, for the purpose of executing the aforementioned scheme and
20 artifice, and attempting to do so, the defendant, RAJNINDER JUTLA, did knowingly
21 submit, and cause to be submitted, to the below listed insurance companies and PBM's,
22 for the patients identified below, the false and fraudulent material set forth below:

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Count	Date	Insurance Company/PBM	Patient	Chief Complaint (per Medical Chart)	False or Fraudulent Material
5	9/13/14	OptumRx	E.G.	Chronic shoulder pain.	Medical Chart Note listing ICD-9 code 338.3 (neoplasm-related pain) as diagnosis code associated with Subsys prescription, and listing medical history of skin cancer to obtain prior authorization for Subsys.
6	10/20/14	Express Scripts	A.R.	Chronic low back and neck pain.	Opt-in Form listing ICD-9 code 338.3 (neoplasm-related pain), and 189.0 (malignant neoplasm of the kidney) as applicable diagnosis codes to obtain prior authorization for Subsys.
7	1/20/15	Express Scripts	H.H.	Persistent neck, back and right hip pain.	Opt-in Form listing ICD-9 code 338.3 (neoplasm-related pain) as applicable diagnosis code, and history of breast fibroma, as a rationale for prior authorization for Subsys.
8	4/30/15	OptumRx	M.R.	Persistent neck, arm and low back pain.	Opt-in Form listing history of colon polyps as a rationale for prior authorization for Subsys.
9	5/8/2015	Optum Rx	K.W.	Foot pain, chronic shoulder pain, and back pain.	Opt-in Form listing ICD-9 code 338.3 (neoplasm-related pain) as applicable diagnosis code, and history of cervical cancer as a rationale for prior authorization for Subsys.
10	6/26/15	Express Scripts	S.G.	Chronic neck, back and lower extremity pain.	Opt-in Form listing ICD-9 code 338.3 (neoplasm-related pain), and V10.51 (history of malignant neoplasm of the bladder) as applicable diagnosis codes, and listing pelvic pain residual from cancer as a rationale for prior authorization for Subsys.
11	6/29/15	Cigna	J.B.	Chronic low back pain.	Opt-in Form listing ICD-9 code 338.3 (neoplasm-related pain), and V10.51 (history of malignant neoplasm of bladder) as

1					applicable diagnosis codes for prior authorization for Subsys.
2	12	8/14/15	Moda Health Ins.	J.K.	Persistent neck, back, elbow, and hip pain. Opt-in Form listing ICD-9 code 338.3 (neoplasm- related pain), and V10.82 (history of melanoma) as applicable diagnosis codes, and history of melanoma as a rationale for prior authorization for Subsys.

7 All in violation of 18 U.S.C. §§ 1347 and 2.

8 **ASSET FORFEITURE ALLEGATIONS**

9 The allegations in Count 1 are hereby realleged and incorporated by reference for
10 the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section
11 981(a)(1)(C). Upon conviction of Conspiracy to Pay and Receive Kickbacks, as charged
12 in Count 1, RAJNINDER JUTLA shall forfeit to the United States, pursuant to Title 18,
13 United States Code, Section 981(a)(1)(C), any and all property, real or personal, that
14 constitutes or derives from any proceeds she obtained as a result of the offense.

15 The allegations in Counts 2 through 4 are hereby realleged and incorporated by
16 reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code,
17 Section 982(a)(7). Upon conviction of one or more counts of Receipt of Kickbacks, as
18 charged in Counts 2 through 4, RAJNINDER JUTLA shall forfeit to the United States,
19 pursuant to Title 18, United States Code, Section 982(a)(7), any and all property, real or
20 personal, that constitutes or derives from any proceeds she obtained as a result of the
21 offense(s).

22 The allegations in Counts 5 through 12 are hereby realleged and incorporated by
23 reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code,
24 Section 982(a)(7). Upon conviction of one or more counts of Healthcare Fraud, as
25 charged in Counts 5 through 12, RAJNINDER JUTLA shall forfeit to the United States,
26 pursuant to Title 18, United States Code, Section 982(a)(7), any and all property, real or
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1 personal, that constitutes or derives from any proceeds she obtained as a result of the
2 offense(s).

3 Substitute Assets. If any of the property described above, as a result of any act or
4 omission of the defendant:

5 a. cannot be located upon the exercise of due diligence;
6 b. has been transferred or sold to, or deposited with, a third party;
7 c. has been placed beyond the jurisdiction of the Court;
8 d. has been diminished in value; or,
9 e. has been commingled with other property which cannot be divided without
10 difficulty,

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1 it is the intent of the United States, pursuant to Title 21, United States Code, Section
2 853(p) and Title 28, United States Code, Section 2461(c), to seek the forfeiture of any
3 other property of the Defendant, up to the value of the above-described forfeitable
4 property.

5 A TRUE BILL:

6 DATED: 7-24-2019

7
8 *Signature of the foreperson is redacted*
9 *pursuant to the policy of the Judicial*
10 *Conference of the United States*

11 FOREPERSON

12 
13
14 BRIAN T. MORAN
15 United States Attorney

16
17 
18 ANDREW C. FRIEDMAN
19 Assistant United States Attorney

20
21 
22 MATTHEW D. DIGGS
23 Assistant United States Attorney

24
25
26
27
28
INDICTMENT - 22
RAJNINDER JUTLA

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